

U.S. DEPARTMENT OF COMMERCE
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PB-252 257

GUIDELINES FOR DEMONSTRATION PROJECT QUALITY
ASSURANCE PROGRAMS

RESEARCH TRIANGLE INSTITUTE

PREPARED FOR
INDUSTRIAL ENVIRONMENTAL RESEARCH LABORATORY

MARCH 1976

132100

EPA-600/2-76-081

March 1976

PB 252 257

Environmental Protection Technology Series

GUIDELINES FOR DEMONSTRATION PROJECT QUALITY ASSURANCE PROGRAMS



REPRODUCED BY
**NATIONAL TECHNICAL
INFORMATION SERVICE**
U. S. DEPARTMENT OF COMMERCE
SPRINGFIELD, VA. 22161

Industrial Environmental Research Laboratory
Office of Research and Development
U.S. Environmental Protection Agency
Research Triangle Park, North Carolina 27711

TECHNICAL REPORT DATA
(Please read instructions on the reverse before completing)

1. REPORT NO. EPA-600/2-76-081	2.	3. RECIPIENT'S ACCESSION NO.
4. TITLE AND SUBTITLE Guidelines for Demonstration Project Quality Assurance Programs		5. REPORT DATE March 1976
		6. PERFORMING ORGANIZATION CODE
7. AUTHOR(S) James Buchanan		8. PERFORMING ORGANIZATION REPORT NO.
9. PERFORMING ORGANIZATION NAME AND ADDRESS Research Triangle Institute P.O. Box 12194 Research Triangle Park, NC 27709		10. PROGRAM ELEMENT NO. EHB-557; ROAP ABA-011
		11. CONTRACT/GRANT NO. 68-02-1398, Task 20
12. SPONSORING AGENCY NAME AND ADDRESS EPA, Office of Research and Development Industrial Environmental Research Laboratory Research Triangle Park, NC 27711		13. TYPE OF REPORT AND PERIOD COVERED Task Final; 7-12/75
		14. SPONSORING AGENCY CODE EPA-ORD

15. SUPPLEMENTARY NOTES **Project officer for this report is L. D. Johnson, Mail Drop 62, Ext 2557.**

16. ABSTRACT **The report presents general guidelines for planning and implementing quality assurance programs at EPA/IERL-RTP demonstration projects. Because quality assurance, a system of activities whose purpose is to assure that overall quality is being controlled effectively, requires a thorough understanding of quality control, the report initially addresses the major components of a project quality control program, including a discussion of quality control in the request for proposal, the proposal, and the work plan. The two major functional areas of quality assurance are the qualitative systems review and the quantitative performance audit. A detailed checklist is provided to aid in the systems review, and three tables provide general information on available techniques for the performance audit. These tables cover the auditing of physical measurements, gas effluent streams, and liquid process streams. The report is designed for project officers, contractors, and others concerned with quality assurance programs at IERL-RTP demonstration projects.**

PRICES SUBJECT TO CHANGE

17. KEY WORDS AND DOCUMENT ANALYSIS			
a. DESCRIPTORS		b. IDENTIFIERS/OPEN ENDED TERMS	c. COSATI Field/Group
Air Pollution	Measurement	Air Pollution Control	13B
Quality Assurance	Flue Gases	Stationary Sources	13H, 14D 21B
Quality Control	Industrial Processes	Liquid Process Streams	14B
Systems			05A
Reviewing			
Performance			
Auditing			
18. DISTRIBUTION STATEMENT Unlimited		19. SECURITY CLASS (This Report) Unclassified	21. NO. OF PAGES 63
		20. SECURITY CLASS (This page) Unclassified	22. PRICE \$4.50-2.25

EPA-600/2-76-081
March 1976

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QUALITY ASSURANCE PROGRAMS

by

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Contract No. 68-02-1398, Task 20
ROAP No. ABA-011
Program Element No. EHB-557

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Research Triangle Park, NC 27711

Prepared for

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Research and Development
Washington, DC 20460

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ACKNOWLEDGMENTS

The work on this project was performed by the Systems and Measurements Division of the Research Triangle Institute. Mr. Frank Smith, Supervisor, Quality Assurance Section, served as the Project Leader. Dr. James Buchanan of the Quality Assurance Section was responsible for the coordination of the program. Institute staff members Dr. D. E. Wagoner and Mr. Larry Hackworth, analytical chemists, Mr. Leon Bisette, an electrical engineer, and Dr. Buchanan, a physical chemist, were major contributors to the program. Project Officer for the Environmental Protection Agency was Dr. L. D. Johnson of the Process Measurements Branch of the Industrial Environmental Research Laboratory. The Research Triangle Institute acknowledges the cooperation and assistance of the Project Officer and Dr. R. Statnick of the Process Measurements Branch. The Institute also appreciates the assistance and guidance provided by Mr. John Williams, the EPA Project Officer for the Shawnee wet limestone scrubber demonstration. Finally, gratitude is extended to Mr. Joe Barkley and Mr. Ken Metcalf of TVA and Mr. Dewey Burbank of Bechtel Corporation for their cooperation at the Shawnee test site.

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1.0 INTRODUCTION

The major objective of this project was to develop a general quality assurance (QA) program for EPA demonstration projects, using the wet limestone scrubber facility at the Shawnee steam plant, Paducah, Kentucky, as an example project. A second objective was to field test the QA program at the Shawnee facility and carry out whatever modifications were necessary in light of that field trial.

In order to facilitate the following discussion it is useful to define three terms; namely, quality, quality control (QC) and quality assurance. It is sometimes difficult to distinguish QC from QA unless the proper definitions are kept in mind. The following is taken from the handbook, Glossary and Tables for Statistical Quality Control.^{*}

1. Quality: The totality of features and characteristics of a product or service (such as measurement data) that bear on its ability to satisfy a given need.

2. Quality control: The overall system of activities whose purpose is to provide a quality of product or service that meets the needs of users; also, the use of such a system.

The aim of quality control is to provide quality that is satisfactory, adequate, dependable, and economic. The overall system involves integrating the quality aspects of several related steps, including the proper specification of what is wanted; production to meet the full intent of the specification; inspection to determine whether the resulting product or service is in accordance with the specification; and review of usage to provide for revision of specification.

3. Quality assurance: A system of activities whose purpose is to provide assurance that the overall quality control job is in fact being done effectively. The system involves a continuing evaluation of the adequacy and effectiveness of the overall quality control program with a view to having corrective measures initiated where necessary. For a specific product or service, this involves verifications, audits, and the evaluation of the quality factors that affect the specification, production, inspection, and use of the product or service.

^{*} American Society for Quality Control, Milwaukee, Wisconsin 53203 (1973).

In summation, the purpose of QA is to independently assess QC. This assessment of QC should take place in two ways. Reviews and performance audits should be conducted by the QC organization itself (an internal inspection program), and in addition there should be periodic assessments by an independent, outside organization.

It is appropriate to delineate the elements of a comprehensive demonstration project QC program. These elements must be evaluated, point-by-point, when QA is integrated into the project.

The organization of this report, then, is as follows: section 2.0 discusses the major components of a QC program, including EPA's responsibility with respect to the project RFP and the contractor's responsibility with respect to the proposal and the work plan; section 3.0 covers the recommended QA program, including the on-site systems review and the quantitative performance audit.

2.0 MAJOR COMPONENTS OF A QUALITY CONTROL PROGRAM

2.1 Quality Assurance Aspects of the RFP

The design of the RFP is predicated on stating as clearly as possible what the objectives of the project are; e.g., to design, construct and maintain a given control system, systematically examining the interaction of appropriate system parameters. The quality of the data obtained from the project will depend upon numerous factors--instrumentation, personnel, sampling technique, sample size, statistical expertise. It is therefore critical that the RFP be as explicit as possible^{*} in delineating two things--what quality data are expected, and how that quality is to be insured.

The following kinds of questions should be answered in the RFP: Is the contractor required to estimate just precision or both precision and bias of his estimates? What number of samples is required for statistical analysis? If confidence limits or tests of significance are required, it may be appropriate at this point to state the significance level he is to use. Are control charts to be used? If an experimental design is required, what factors is the contractor to consider (at a minimum) in designing his experiment and what other factors might be considered if time and funds are sufficient? What instruments should the contractor use (if it is reasonable to specify these) and what time unit(s) should be used for analysis? When is the contractor required to analyze his data and give the results of this analysis (e.g., only at the end of the project or throughout the project)? How exactly is the contractor to express precision and/or bias and for which estimates? Some or all of these items may necessarily be suggested by the bidder.

Since RFPs are limited in length, it would, in most cases be inappropriate to include more than a brief (one or two paragraph) statement of QC requirements. Nevertheless, it is most important that the bid solicitation be as explicit as possible concerning QC. For illustrative purposes, a sample statement appropriate to a wet limestone sulfur dioxide scrubbing demonstration project is given below:

* It is understood that, because of the nature of the proposed work, it may not be possible to specify either the expected data quality or the way in which data quality is to be assured.

"Precision and bias estimates, based on statistically significant sample sizes, must be provided for such critical process parameters as temperature, pressure, flow rate and chemical composition in both the liquid slurry and gas effluent streams, measured at scrubber inlet and outlet. These estimates should generally be set at the 90 per cent confidence level. Control charts must be used continuously for each critical parameter.

Interaction of major process parameters must be determined by a factorial or partial factorial method. Instrumentation must be appropriate for each measurement; e.g., determination of calcium and magnesium in slurry solids must be by a method yielding precision and accuracy comparable to that of x-ray fluorescence. Standards must be analyzed by at least two independent outside laboratories, and agree within 5 per cent of the mean value. Control samples must be used at appropriate (cost-effective) intervals to serve as internal audits of the analytical procedures. Proposals must provide a statistically sound plan, in detail, for implementing the quality assurance program as outlined above, and must provide for monthly data reports which include statistical treatment of current data."

2.2 Evaluation of Quality Control in the Proposal

The proposal should contain a statement as to the precise position the bidder's company takes regarding quality control programs. This should include past projects and the quality control program effectiveness in that project. In particular, there should be a clear and explicit response to the QC requirements stated in the RFP. This response must be compared directly, item-by-item, with other proposals submitted against the RFP. The evaluation should result in a determination of a "figure of merit" for the bidder's quality control organization and the competence of the staff. For a project requiring a high degree of professionalism, this may require an on-site audit of the facility and personnel as part of EPA's QA program for that contract/project. Such audits should enhance the overall understanding of the submitted proposal as it relates to the requirements of the RFP.

The bid should contain a list of reports on previous work which will allow, if desired, an investigation of how the contractor has performed in producing good data quality and presenting the data in a precise and meaningful manner. Investigation of the above reports should include an examination of the use of appropriate statistical techniques, such as analysis of variance and regression. Past experience of the contractor in designing and analyzing experiments will be an indication of his expertise in carrying out a test program.

The bidder's proposal should directly address the data accuracy requirements contained in the RFP. It should provide qualitative evidence as to his ability to meet the accuracy requirements. These statements should include methods of statistical analysis to be employed to provide the degree of confidence necessary for the work. His statement should also include formats for the presentation of raw data, report data, and data derived from data analysis.

The contractor should indicate how he intends to insure good quality data (control charts, calibration procedures, etc.). What sample sizes are his statistics to be based upon and what is his justification for these sample sizes?

Procedures should be defined for day-to-day recordkeeping and data analysis which will permit prompt discovery of out-of-tolerance data, investigation into the cause of the problem and formal reporting to the Project Officer.

Document control, covering test specifications and procedures, sampling devices, sampling instrumentation, calibration equipment, maintenance and calibration procedures, and other related documents, should be indicated in the proposal. The control should include a center for issuing new documents and retrieving out-of-date documents, with spot checks on the documents in current usage.

The bidder should furnish a statement regarding the procurement procedures to be followed in purchasing equipment and supplies directly relating to those items required for the work to be done. He should also specify the controls to be used to insure receipt, storage and use of the purchased items.

The proposal should include a personnel program outline for the training and evaluation of skills required to complete the work. The above program should be based on a periodic review and evaluation of performance.

There should be provision for changes in procedures when it is evident that data being obtained is not sufficiently accurate or appropriate for the intent of the project as outlined by the Project Officer.

If a contractor has a good proposal but is unclear on some phases of data quality, it would seem worthwhile to have him clarify his proposal by asking him to answer specific questions. If the answers to these questions are still vague, it is a good indication that the quality for these phases of the project may be questionable were this contractor to carry out the project.

2.3 Evaluation of Quality Control in the Work Plan

The work plan should be a detailed accounting of the actual steps to be taken to complete the work delineated in the proposal and should be in direct accord with the requirements of the RFP and other agreements with the Project Officer. Particular attention should be placed on the areas discussed below in order to realize the collection of data having acceptable precision, accuracy, representativeness and completeness.

In cases where the submitted proposal has been accepted but lacks the completeness required by the Project Officer, finalized negotiations to remove the problem areas should be directly addressed in the work plan showing the details of the work to be done.

The work plan must be submitted to the Project Officer before any work is begun by the contractor. The plan can be accepted in draft form which will allow for minor changes prior to the final plan's acceptance and approval. (see RFP criteria).

There should be a description of the layout of all equipment and instrumentation to be used for measurement and calibration and their specific use in the program. The layout should show the positions of measurement probes and sensors with a discussion of the rationale used to warrant the positions chosen. Operating instructions (test procedures) for each of the above items and their supporting equipment should be included. These procedures must show expected and acceptable limits of measurement accuracies including the bias of each item and its own built-in tolerances and errors resulting from calibration deficiencies. Maintenance and calibration instructions should also be included. Calibration techniques must be in agreement with nationally accepted practices, using standards that are traceable to primary standards.

The Project Officer^{*} should examine all test methods to determine their concurrence with standard practices. Innovative measurement techniques must be evaluated for applicability and reliability. He should examine the environment around the sampling equipment for error-producing situations. He should examine all operating procedures for possible measurement inaccuracies due to sampling methods, use of equipment, calibration of equipment, ineffective

^{*} or his designate.

maintenance procedures or lack of proper personnel. There should also be an examination of statistical analysis techniques for appropriateness, and statements concerning the confidence levels of data to be reported should be carefully scrutinized.

The work plan should include a systems analysis program to provide early detection of measurement problems based on periodic data reports, as well as results of all audits. The analysis program should include provisions for transmission of such problem information to the Project Officer and the initiation of the appropriate corrective action. There should also be provisions for alternate measurement techniques to be substituted for procedures that may prove to be faulty, in that the kind of data and/or its accuracy are not appropriate for the project goals. The provisions should also allow for program changes to increase the accuracy and reliability of data which prove to be of more importance than originally called for. The provisions should contain adequate documentation, including the necessary approval for the Project Officer.

Finally, the work plan should provide an effective procurement program for all equipment, materials, and supplies being used for the taking of data. This should include plans for controlled receipt, storage, and distribution of the above items.

2.4 Management Commitment to Quality Control

No QC program, regardless of the amount of planning or level of effort expended, will be effective without the explicitly visible support of top management. The support should be expressed initially as the project gets under way, and periodically throughout the duration of the program. The support of top management then filters down through middle and lower management to the operators, resulting in a program where QC is practiced on a day-to-day basis, rather than being an additional problem or nuisance. Quality Control must be a built-in, functional area within the total program, and this is not possible without continuing, obvious management support.

2.5 Quality Control in the Organizational Structure

Support for quality control is most visible when the organizational structure has provision for personnel whose authority and responsibilities lie in the area; i.e., a Quality Control Coordinator (QCC) and/or any other staff appropriate to the program. The QCC is responsible for the organization's entire QC program, and his judgment determines the effectiveness of the program. The basic function of the QCC should be the fulfillment of the QC objectives of management, in the most efficient and economical manner commensurate with insuring continuing completeness, accuracy, and precision of the data produced. The responsibilities and authority of the QCC are detailed in the Quality Assurance Handbook for Air Pollution Measurement Systems, Vol. 1, Principles,^{*} now being prepared by the Environmental Protection Agency.

The QCC should have, within the main organizational structure, a subordinate organization for QC activities (auditing, calibration, quality control). He should have authority for assignment of QC duties and for coordination of the entire program, and must not be directly subordinate to operational personnel in the project.

2.6 Assessment of Quality Control Requirements

The establishment of a quality control program for a demonstration project requires first of all the setting, in as quantitative manner as possible, of project objectives. The desired precision and accuracy of each measurement should be specified, as well as the technical means of attaining this degree of data quality; i.e., the tasks to be performed. Once this is done, it is efficient to group the tasks organizationally and assign responsibility for the QC function in each task-group. It is inevitable that problems are incurred in each step of the planning and establishment of the QC program. Some of these cannot be resolved until the program enters the functional stage. What is important initially is that these problems be identified and clearly stated, so that they can be resolved as quickly as possible once the program gets under way.

^{*} Some of the general discussion of QC programs in this report has been taken from this document.

2.7 Specific Areas of Concern for Demonstration Project Quality Control Program

A Quality Control program for a demonstration project serves to:

1. Evaluate the overall adequacy of the project insofar as data quality is concerned.
2. Identify potential as well as existing problems in the data-producing system, from measurement to data reduction.
3. Stimulate research into and discussion of alternative methods for obtaining data of the required quality.

It is advisable to delineate a number of important aspects of the project which have direct bearing on data quality, and to discuss each of these in some detail.

2.7.1 Facilities and Equipment

An obvious beginning point in the assessment of an ongoing program is a general survey of the facilities and equipment available for day-to-day operation of the project. Are they adequate for the job at hand? Do standards exist for evaluation of facilities, equipment and materials?

The laboratories, data processing and other operational areas should be neat and orderly, within common-sense limits imposed by the nature of the facility. Laboratory benches, particularly areas where critical operations such as weighing are carried out, should be kept clear of all but necessary tools, glassware, etc. Personal items (coats, hats, lunch boxes) should not be left in the working area. Provision must be made for storage of these items in personal lockers or the like. A neat, well-organized laboratory area serves to inspire neatness and organization among the laboratory workers.

Good laboratory maintenance, particularly for certain types of instrumentation, requires complete manuals, kept in a convenient place so that they are readily available to appropriate personnel. Responsibility for keeping up with all necessary manuals should be given to an individual, with the understanding that he must devise a system (checkin-checkout) for quick location of each document.

2.7.2 Configuration Control

The documentation of design changes in the system must be carried out unflinchingly. Procedures for such documentation should be written, and be accessible to any individual responsible for configuration control. It is all too easy, as the system is modified repeatedly, to allow one key man to hold, largely by memory only, great amounts of vital information. This information would be virtually totally lost if this key man were no longer available. Engineering schematics should be maintained current on both the system and subsystem level, and all computer programs listed and flow charted. Changes in computer hardware and software must be documented, even when such changes are apparently trivial. Significant design changes must be documented and forwarded to the EPA Project Officer, by way of established procedure.

2.7.3 Personnel Training

It is highly desirable that there be a programmed training system for new employees. This system should include motivation toward producing data of acceptable quality standards. A part of the program should involve "practice work" by the new employee. The quality of the work can be immediately verified and discussed by the supervisor, with appropriate corrective action taken. This system is to be preferred to on-the-job training, which may be excellent or slipshod, depending upon a number of circumstances.

Key personnel (laboratory supervisors, senior engineers) should be required to document their specialized knowledge and techniques, so far as is possible. They should each be required to develop an assistant, if the program personnel situation allows, who could take responsibility when the senior man is unavailable. A most undesirable situation arises when replacement personnel must be brought in and forced to gain knowledge of the program through the experience of trial and error. This is not an infrequent occurrence, however, when budgeting constraints override other priorities.

A thorough personnel training program should focus particular attention on those people whose work directly affects data quality (calibration personnel, bench chemists, etc.). These people must be cognizant of the quality standards fixed for the project and the reasons for those standards. They must be made aware of the various ways of achieving and maintaining quality data. As these

people progress to higher degrees of proficiency, their accomplishments should be reviewed and then documented. A motivating factor for high performance could be direct and obvious rewards (monetary, status or both), awarded in a manner visible to other comparable personnel.

2.7.4 Documentation Control

Procedures for making revisions to technical documents must be clearly written out, with the lines of authority indicated. The revisions themselves should be written and distributed to all affected parties, thus insuring that the change will be implemented and will become permanent. If a technical document change pertains to an operational activity, that change should be analyzed for side effects. The change should not be rendered permanent until any harmful side effects have been controlled.

Revisions to computer software should be written, with lines of authority indicated. Reasons for the changes must be clearly spelled out. The revisions should be written and distributed to all affected parties.

2.7.5 Control Charts

Control charts are essential as a routine day-to-day check on the consistency or "sameness" of the data precision. A control chart should be kept for each measurement that directly affects the quality of the data. Typically, control charts are maintained for duplicate analyses, percent isokinetic sampling rate, calibration constants, and the like. An example control chart is given as figure 1. The symbol σ (sigma) represents a difference, d , of one standard deviation unit in two duplicate measurements, one of which is taken as a standard, or audit value. Two σ is taken as a warning limit and 3σ as a control limit. If a laboratory measurement differs from the audit value by more than 3σ , the technique is considered out-of-control. Control charts are dealt with in depth in a number of standard texts on quality control of engineering processes.*

* Quality Assurance Handbook for Air Pollution Measurement Systems, Volume 1, Principles, being prepared by the Environmental Protection Agency.

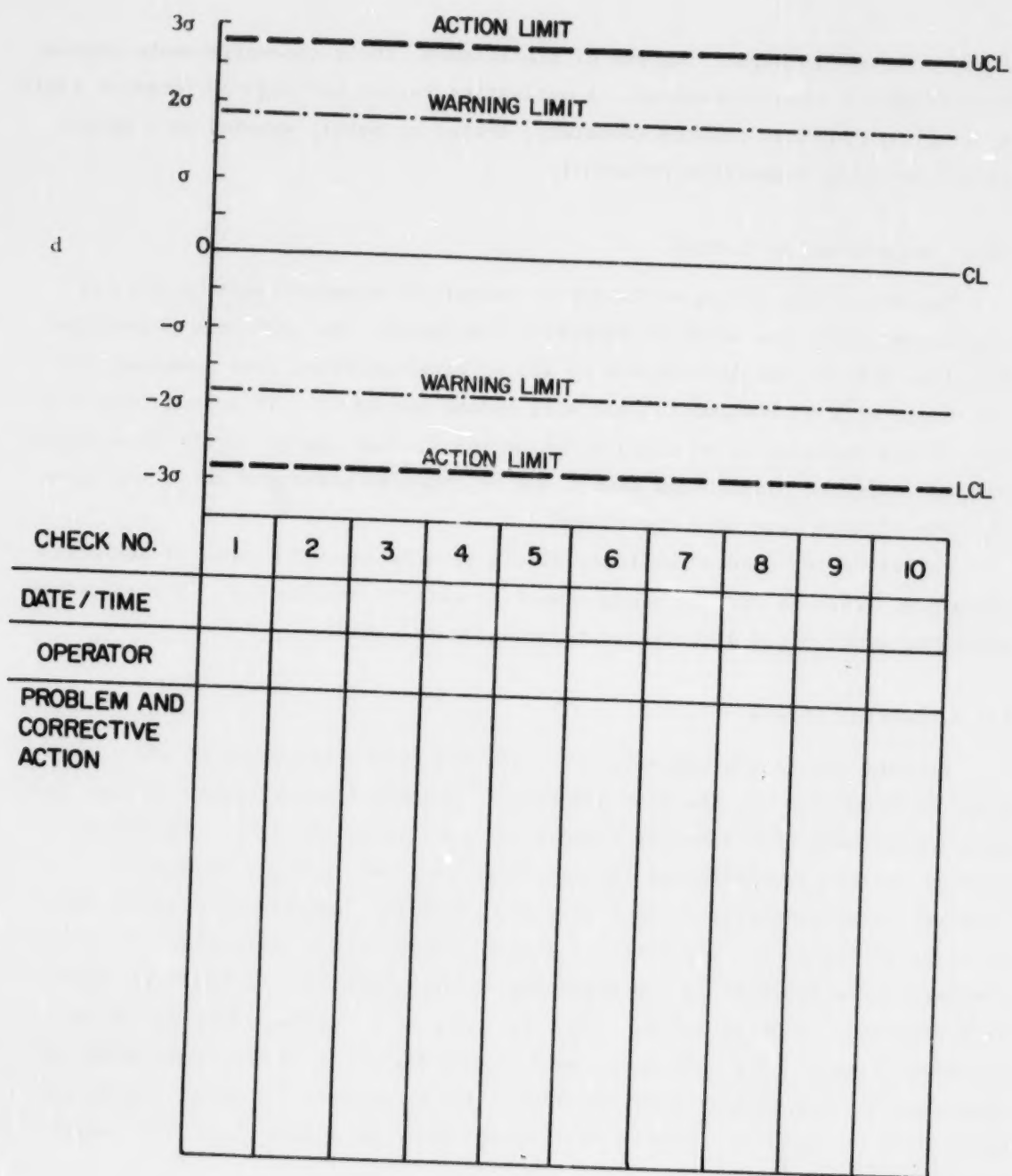


Figure 1. Standard quality control chart.

2.7.6 In-Process Quality Control

During routine operation, critical measurement methods should be checked for conformance to standard operating conditions (flow rates, reasonableness of data being produced and the like). The capability of each method to produce data within specification limits should be ascertained by means of appropriate control charts. When a discrepancy appears in a measurement method, it should be analyzed and corrected as soon as possible.

For all standard methods, the operating conditions must be clearly defined in writing, with specific reference to each significant variable. Auxiliary measuring, gaging, and analytical instruments should be maintained operative, accurate, and precise by regular checks and calibrations against stable standards which are traceable to a primary standard, preferably furnished by the U.S. Bureau of Standards (if available).

2.7.7 Procurement and Inventory Procedures

There should be well-defined and documented purchasing guidelines for all equipment and reagents having an effect on data quality. Performance specifications should be documented for all items of equipment having an effect on data quality. Chemical reagents considered critical to an analytical procedure are best procured from suppliers who agree to submit samples for testing and approval prior to initial shipment. In the case of incoming equipment, there should be an established and documented inspection procedure to determine if procurements meet the quality assurance and acceptance requirements. The results of this inspection procedure should be documented.

Whenever discrepant materials are detected, this information should be immediately transmitted to the supplier, for satisfaction. The materials are either returned or disposed of, at the discretion of the quality control supervisor.

Once an item has been received and accepted, it should be documented in a receiving record log giving a description of the material, the data of the receipt, results of the acceptance test, and the signature of the responsible individual. It is then placed in inventory, which should be maintained on a first-in, first-out basis. It should be identified as to type, age and

acceptance status. In particular, reagents and chemicals which have limited shelf life should be identified as to shelf life expiration date and systematically issued from stock only if they are still within that date.

2.7.8 Preventive Maintenance

It is most desirable that preventive maintenance procedures be clearly defined and written for each measurement system and its support equipment. When maintenance activity is necessary, it should be documented on standard forms maintained in log books. A history of the maintenance record of each system serves to throw light on the adequacy of its maintenance schedule and parts inventory.

2.7.9 Reliability

The reliability of each component of a measurement system relates directly to the probability of obtaining valid data from that system. It follows that procedures for reliability data collection, processing and reporting should be clearly defined and in written form for each system component. Reliability data should be recorded on standard forms and kept in a log book. If this procedure is followed, the data can be utilized in revising maintenance and/or replacement schedules.

2.7.10 Data Validation

Data validation procedures, defined ideally as a set of computerized and manual checks applied at various appropriate levels of the measurement process, should be clearly defined, in written form, for all measurement systems. Criteria for data validation must be documented and include limits on: (1) operational parameters such as flow rates; (2) calibration data; (3) special checks unique to each measurement; e.g., successive values/averages; (4) statistical tests, e.g., outliers; and (5) manual checks such as hand calculations. The limits must be adequate to insure the detection of invalid data with a high probability, for all or certainly most of the measurement systems. The required data validation activities (flow-rate checks, analytical precision, etc.) must be recorded on standard form in a log book.

A summary of validation procedures should be prepared at each level or critical point in the measurement process and forwarded to the next level with the applicable block of data. Any invalidated data should be so indicated. The procedures for considering such data invalid must be clearly understood at all levels where such data is to be used, and thus these procedures must be written and available for scrutiny and comment. Where possible, validation criteria should be computerized and data are automatically invalidated.

Any demonstration project should, on a random but regular basis, have quality audits performed by in-house personnel. These audits must be independent of normal project operations, preferably performed by the QCC or his appointees. The audits should be both qualitative and quantitative (i.e., they should include both system reviews and independent measurement checks). For the system review, a checklist is desirable to serve as a guide for the reviewer. Such a checklist is included as appendix A of this report.

The quantitative aspect of the audit will vary depending on the nature of the project. Some guidelines for quantitative audits are given in appendix B.

2.7.11 Feedback and Corrective Action

Closely tied to the detection of invalid data is the problem of establishment of a closed loop mechanism for problem detection, reporting and correction. Here it is important that the problems are reported to those personnel who can take appropriate action. A feedback and corrective action mechanism should be written out, with individuals assigned specific areas of responsibility. Again, documentation of problems encountered and actions taken is most important. Standard forms, kept in a log book, are recommended. A periodic summary report on problems and corrective action should be prepared and distributed to all levels of management. This report should include: a listing of major problems for the reporting period; names of persons responsible for corrective actions; criticality of problems; due dates; present status; trend of quality performance (i.e., response time, etc.); a listing of items still open from previous reports.

2.7.12 Calibration Procedures

Calibration procedures are the crux of any attempt to produce quality data from a measurement system. For this reason it is extremely important that the procedures be technically sound and consistent with whatever data quality requirements exist for that system. Calibration standards must be specified for all systems and measurement devices, with written procedures for assuring, on a continuing basis, traceability to primary standards. Since calibration personnel change from time to time, the procedures must be, in each instance, clearly written in step-by-step fashion. Frequency of calibration should be set and documented, subject to rescheduling as the data are reviewed. Full documentation of each calibration and a complete history of calibrations performed on each system are absolutely essential. This permits a systematic review of each system reliability.

3.0 GUIDELINES FOR DEMONSTRATION PROJECT QUALITY ASSURANCE PROGRAMS

3.1 General Statements

The objective of quality assurance is to independently assess the quality control program of the project. This assessment should normally take two major forms: (1) a qualitative on-site systems review, and (2) a quantitative performance audit. These are discussed in detail below, as sections 3.2 and 3.3, respectively.

The frequency of a systems review and/or a performance audit obviously should be dictated by the specific project. It is recommended that a minimum frequency be once each calendar year. The initial systems review and performance audit should take place within the first quarter of the first project year. Subsequent scheduling should be dependent on the requirements of management and the apparent quality of the day-to-day data being obtained. More frequent auditing may be necessary in the initial stages of the project.

3.2 The On-Site Qualitative System Review

The objective of the on-site qualitative systems review is to assess and document facilities; equipment; systems documentation; operation, maintenance, and calibration procedures; recordkeeping; data validation; and reporting aspects of the total quality control program for a demonstration project. The review should accomplish the following:

1. Identify existing system documentation, i.e., maintenance manuals, organizational structure, operating procedures, etc.
2. Evaluate the adequacy of the procedures as documented.
3. Evaluate the degree of use of and adherence to the documented procedures in day-to-day operations based on observed conditions (auditor) and a review of applicable records on file.

To aid the auditor in performing the review, a checklist is included as appendix A.

3.3 The Performance Audit

In addition to a thorough on-site systems review, quantitative performance audits should be periodically undertaken at each demonstration project. The

objective of these audits is to evaluate the validity of project data by independent measurement techniques. It is convenient to classify the major measurement methods into three areas: physical measurements, gas stream measurements and liquid stream measurements (the latter including analysis of any suspended solids). Appendix B lists in matrix form a number of standard techniques for auditing in the three major areas just mentioned. Table 1 is a compilation of commonly measured physical properties, with a selection of possible measurement, calibration and audit techniques. Table 2, concentrating on analysis of gas effluent streams, lists the material to be analyzed, and measurement, calibration and audit techniques for that material. Finally table 3 very briefly and generally deals with measurement methods appropriate to liquids and solids. The specific techniques vary widely from project to project, but the audit technique generally involves use of control (reference) samples of known composition and/or splitting a sample among several laboratories for independent analyses.

3.4 Material Balances

Material balance serves as a gross indication of the validity of the total measurement system complex of the project. The extent of closure will be directly related to the precision and bias of each measurement taken. In general, both physical measurements of flow rates, temperatures, pressures (and so on), and chemical analyses of material composition will bear on the degree of closure attained. The achievable extent of closure must be estimated for each project and used as a target figure. The frequency with which material balances are run is related to how successful one is in attaining the estimated closure over a significant period of time.

3.5 Assessment of Data Quality

Standard methods exist for estimation of the precision and accuracy of measurement data. Efficient usage of the audit data requires that a rationale be followed which gives the best possible estimates of precision and accuracy within the limits imposed by timing, sample size, etc.

For a given measurement, the difference between the field (or plant) result and the audited,

$$d_j = X_j - X_{aj} ,$$

is used to calculate a mean and standard deviation as follows:

$$\bar{d} = \sum_{j=1}^n d_j / n ,$$

$$s_d = \left[\sum_{j=1}^n (d_j - \bar{d})^2 / (n - 1) \right]^{1/2} .$$

Now $\bar{d}$ is an estimate of the bias in the measurements (i.e., relative to the audited value). Assuming the audited data to be unbiased, the existence of a bias in the field data can be checked by the appropriate t-test, i.e.,

$$t = \frac{\bar{d} - 0}{s_d / \sqrt{n}} .$$

If t is significantly large, say greater than the tabulated value of t with $n - 1$ degrees of freedom, which is exceeded by chance only 5 per cent of the time, then the bias is considered to be real, and some check should be made for a possible cause of the bias. If t is not significantly large, then the bias should be considered zero, and the accuracy of the data is acceptable.

The standard deviation s_d is a function of both the standard deviation of the field measurements and of the audit measurements. Assuming the audit values to be much more accurate than the field measurements, then s_d is an estimate of $\sigma\{X\}$, the population standard deviation for the measurements. For example, the estimated standard deviation, s_d , may be directly checked against the assumed value, $\sigma\{X\}$, by using the statistical test procedure

$$\frac{\chi^2}{f} = \frac{s_d^2}{\sigma^2\{X\}} ,$$

where χ^2/f is the value of a random variable having the chi-square distribution with $f = n - 1$ degrees of freedom. If χ^2/f is larger than the tabulated value exceeded only 5 percent of the time, then it would be concluded that the test procedure is yielding more variable results due to faulty equipment or operational procedure.

The measured values should be reported along with the estimated biases, standard deviations, the number of audits, n , and the total number of field tests, N , sampled ($n \leq N$). Estimates (such as s_d and $\bar{d}$) which are significantly different from the assumed population parameters should be identified on the data sheet.

The t -test and χ^2 -test described above are used to check on the biases and standard deviations separately.

Other statistical techniques exist which may apply to specific projects (or to highly specialized areas of a given project). It is usually well worth your while to acquire the services of a statistical consultant in order to most effectively treat the available data.

4.0 ASSESSMENT AND MODIFICATION OF THE ONGOING QUALITY ASSURANCE PROGRAM

The guidelines put forth in the preceding sections serve as a basis for development of a Quality Assurance program specific to the needs of a particular project. A program should not be attempted without a thorough study of the entire facility, supplemented by at least one site visit. It is to be desired that provision for QA be made from the project's inception. The EPA Project Officer's responsibility is then to see that a program of adequate QA practices is incorporated into the day-to-day project operations, along with periodic QA audits conducted by outside organizations.

Implementation of the program, at whatever point in the lifetime of the project, exposes weaknesses of approach and problems which were not anticipated in the planning stages. Certainly it is necessary to maintain maximum flexibility of approach as the interface with project realities is made. The report on the short-term QA program conducted at the EPA wet limestone SO₂ scrubber facility at Shawnee Steam Plant (Paducah, Kentucky), documents several problems of implementation and suggests procedures for avoiding those problems in future efforts.

Generally, one should expect that a degree of modification would be required in the areas listed below:

1. audit instrumentation and general equipment requirements
2. sampling frequencies
3. audit personnel requirements.

Experience must always be the final judge of the effectiveness of a Quality Assurance program, as one monitors data quality on a continuing basis.

APPENDIX A QUALITATIVE AUDIT CHECKLIST FOR DEMONSTRATION PROJECTS

This checklist gives three descriptions to each facet of a typical quality control system. In all cases the "5" choice indicates the most desirable and effective mode of operation; "3" is marginal and tolerable; "1" is definitely unacceptable and ineffective as a mode of operation.

It is not always possible to describe accurately all options with only three choices. Therefore, a "2" or "4" rating may be selected if the evaluator feels that an inbetween score is more descriptive of the actual situation.

After all the applicable questions are answered, an average is computed to give an overall indication of the quality control system effectiveness.

Generally, a rating of 3.8 or better is considered acceptable.

A rating between 2.5 and 3.8 indicates a need for improvement but there is not imminent threat to project performance as it now stands.

QUALITY ORGANIZATION

SCORE

- (1) Overall responsibility for quality assurance (or quality control) for the organization is:
 - (a) Assigned to one individual by title (e.g., Quality Control Coordinator). 5
 - (b) Assigned to a specific group within the organization 3
 - (c) Not specifically assigned but left to the discretion of the various operational, analytical, inspection, and testing personnel. 1
- (2) The Quality Control Coordinator is located in the organization such that:
 - (a) He has direct access to the top management level for the total operation independent of others involved in operational activities. 5
 - (b) He performs as a peer with others involved in operational activities with access to top management through the normal chain of command. 3
 - (c) His primary responsibility is in operational activities with quality assurance as an extra or part-time effort. 1
- (3) Data reports on quality are distributed by the Quality Control Coordinator to:
 - (a) All levels of management. * 5
 - (b) One level of management only. 3
 - (c) The quality control group only. 1
- (4) Data Quality Reports contain:
 - (a) Information of operational trends, required actions, and danger spots. 5
 - (b) Information on suspected data/analyses and their causes. 3
 - (c) Percent of valid data per month. 1

* Management at appropriate levels in all applicable organizations such as subcontractors, prime contractor, EPA.

THE QUALITY SYSTEM

SCORE

(5) The quality control system is:

- (a) Formalized and documented by a set of procedures which clearly describe the activities necessary and sufficient to achieve desired quality objectives from procurement through to reporting data to the EPA/RTP.
- (b) Contained in methods procedures or is implicit in those procedures. Experience with the materials, product, and equipment is needed for continuity of control.
- (c) Undefined in any procedures and is left to the current managers or supervisors to determine as the situation dictates.

5

3

1

(6) Support for quality goals and results is indicated by:

- (a) A clear statement of quality objectives by the top executive with continuing visible evidence of its sincerity to all levels of the organization.
- (b) Periodic meetings among operations personnel and the individual(s) responsible for quality assurance on quality objectives and progress toward their achievement.
- (c) A "one-shot" statement of the desire for product quality by the top executive after which the quality assurance staff is on its own.

5

3

1

(7) Accountability for quality is

- (a) Clearly defined for all sections and operators/analysts where their actions have an impact on quality.
- (b) Vested with the Quality Control Coordinator who must use whatever means possible to achieve quality goals.
- (c) Not defined.

5

3

1

THE QUALITY SYSTEM (continued)

SCORE

- (8) The acceptance criteria for the level of quality of the demonstration projects routine performance are:
 - (a) Clearly defined in writing for all characteristics. 5
 - (b) Defined in writing for some characteristics and some are dependent on experience, memory and/or verbal communication. 3
 - (c) Only defined by experience and verbal communication. 1
- (9) Acceptance criteria for the level of quality of the project's routine performance are determined by:
 - (a) Monitoring the performance in a structured program of inter- and intralaboratory evaluations. 5
 - (b) Scientific determination of what is technically feasible. 3
 - (c) Laboratory determination of what can be done using currently available equipment, techniques, and manpower. 1
- (10) Decisions on acceptability of questionable results are made by:
 - (a) A review group consisting of the chief chemist or engineer, quality control, and others who can render expert judgment. 5
 - (b) An informal assessment by quality control. 3
 - (c) The operator/chemist. 1
- (11) The quality control coordinator has the authority to:
 - (a) Affect the quality of analytical results by inserting controls to assure that the methods meet the requirements for precision, accuracy, sensitivity, and specificity. 5
 - (b) Reject suspected results and stop any method that produces high levels of discrepancies. 3
 - (c) Submit suspected results to management for a decision on disposition. 1

IN-PROCESS QUALITY ASSURANCE

SCORE

- (12) Measurement methods are checked:
- (a) During operation for conformance to operating conditions and to specifications, e.g., flow rates, reasonableness of data, etc. 5
 - (b) During calibration to determine acceptability of the results. 3
 - (c) Only when malfunctions are reported. 1
- (13) The capability of the method to produce within specification limit is:
- (a) Known through method capability analysis ($\bar{X}$ -R Charts) to be able to produce consistently acceptable results. 5
 - (b) Assumed to be able to produce a reasonably acceptable result. 3
 - (c) Unknown. 1
- (14) Method determination discrepancies are:
- (a) Analyzed immediately to seek out the causes and apply corrective action. 5
 - (b) Checked out when time permits. 3
 - (c) Not detectable with present controls and procedures. 1
- (15) The operating conditions (e.g., flow rate, range, temperature, etc.) of the methods are:
- (a) Clearly defined in writing in the method for each significant variable. 5
 - (b) Controlled by supervision based on general guidelines. 3
 - (c) Left up to the operator/analyst. 1

IN-PROCESS QUALITY ASSURANCE (continued)

SCORE

(16) Auxillary measuring, gaging, and analytical instruments are:

- | | |
|---|---|
| (a) Maintained operative, accurate, and precise by regular checks and calibrations against stable standards which are traceable to the U. S. Bureau of Standards. | 5 |
| (b) Periodically checked against a zero point or other reference and examined for evidence of physical damage, wear or inadequate maintenance. | 3 |
| (c) Checked only when they stop working or when excessive defects are experienced which can be traced to inadequate instrumentation. | 1 |

CONFIGURATION CONTROL

SCORE

- (17) Procedures for documenting, for the record, any design change in the system are:
- (a) Written down and readily accessible to those individuals responsible for configuration control. 5
 - (b) Written down but not in detail. 3
 - (c) Not documented. 1
- (18) Engineering schematics are:
- (a) Maintained current on the system and subsystem levels. 5
 - (b) Maintained current on certain subsystems only. 3
 - (c) Not maintained current. 1
- (19) All computer programs are:
- (a) Documented and flow charted. 5
 - (b) Flow charted. 3
 - (c) Summarized. 1
- (20) Procedures for transmitting significant design changes in hardware and/or software to the EPA project officer are:
- (a) Documented in detail sufficient for implementation. 5
 - (b) Documented too briefly for implementation. 3
 - (c) Not documented. 1

DOCUMENTATION CONTROL

SCORE

- (21) Procedures for making revisions to technical documents are:
- (a) Clearly spelled out in written form with the line of authority indicated and available to all involved personnel. 5
 - (b) Recorded but not readily available to all personnel. 3
 - (c) Left to the discretion of present supervisors/managers. 1
- (22) In revising technical documents, the revisions are:
- (a) Clearly spelled out in written form and distributed to all parties affected on a controlled basis which assures that the change will be implemented and permanent. 5
 - (b) Communicated through memoranda to key people who are responsible for effecting the change through whatever method they choose. 3
 - (c) Communicated verbally to operating personnel who then depend on experience to maintain continuity of the change. 1
- (23) Changes to technical documents pertaining to operational activities are:
- (a) Analyzed to make sure that any harmful side effects are known and controlled prior to revision effectivity. 5
 - (b) Installed on a trial or gradual basis, monitoring the product to see if the revision has a net beneficial effect. 3
 - (c) Installed immediately with action for correcting side effects taken if they show up in the final results. 1

DOCUMENTATION CONTROL (continued)

SCORE

(24) Revisions to technical documents are:

- | | |
|---|---|
| (a) Recorded as to date, serial number, etc. when the revision becomes effective. | 5 |
| (b) Recorded as to the date the revision was made on written specifications. | 3 |
| (c) Not recorded with any degree of precision. | 1 |

(25) Procedures for making revisions to computer software programs are:

- | | |
|--|---|
| (a) Clearly spelled out in written form with the line of authority indicated. | 5 |
| (b) Not recorded but changes must be approved by the present supervisor/manager. | 3 |
| (c) Not recorded and left to the discretion of the programmer. | 1 |

(26) In revising software program documentation, the revisions are:

- | | |
|--|---|
| (a) Clearly spelled out in written form with reasons for the change and the authority for making the change distributed to all parties affected by the change. | 5 |
| (b) Incorporated by the programmer and communicated through memoranda to key people. | 3 |
| (c) Incorporated by the programmer at his will. | 1 |

DOCUMENTATION CONTROL (continued)

SCORE

- (27) Changes to software program documentation are:
- (a) Analyzed to make sure that any harmful side effects are known and controlled prior to revision effectivity. 5
 - (b) Incorporated on a trial basis, monitoring the results to see if the revision has a net beneficial effect. 3
 - (c) Incorporated immediately with action for detecting and correcting side effects taken as necessary. 1
- (28) Revisions to software program documentation are:
- (a) Recorded as to date, program name or number, etc., when the revision becomes effective. 5
 - (b) Recorded as to the date the revision was made. 3
 - (c) Not recorded with any degree of precision. 1

PREVENTATIVE MAINTENANCE

SCORE

- (29) Preventative maintenance procedures are:
- (a) Clearly defined and written for all measurement systems and support equipment. 5
 - (b) Clearly defined and written for most of the measurement systems and support equipment. 3
 - (c) Defined and written for only a small fraction of the total number of systems. 1
- (30) Preventative maintenance activities are documented:
- (a) On standard forms in station log books. 5
 - (b) Operator/analyst summary in log book. 3
 - (c) As operator/analyst notes. 1
- (31) Preventative maintenance procedures as written appear adequate to insure proper equipment operation for:
- (a) All measurement systems and support equipment. 5
 - (b) Most of the measurement systems and support equipment. 3
 - (c) Less than half of the measurement systems and support equipment. 1
- (32) A review of the preventative maintenance records indicates that:
- (a) Preventative maintenance procedures have been carried out on schedule and completely documented. 5
 - (b) The procedures were carried out on schedule but not completely documented. 3
 - (c) The procedures were not carried out on schedule all the time and not always documented. 1

PREVENTATIVE MAINTENANCE (continued)

SCORE

(33) Preventative maintenance records (histories) are:

- | | |
|---|---|
| (a) Utilized in revising maintenance schedules, developing an optimum parts/reagents inventory and development of scheduled replacements to minimize wear-out failures. | 5 |
| (b) Utilized when specific questions arise and for estimating future work loads. | 3 |
| (c) Utilized only when unusual problems occur. | 1 |

DATA VALIDATION PROCEDURES

SCORE

(34) Data validation procedures are:

- (a) Clearly defined in writing for all measurement systems. 5
- (b) Defined in writing for some measurement systems, some dependent on experience, memory, and/or verbal communication. 3
- (c) Only defined by experience and verbal communication. 1

(35) Data validation procedures are:

- (a) A coordinated combination of computerized and manual checks applied at different levels in the measurement process. 5
- (b) Applied with a degree of completeness at no more than two levels of the measurement process. 3
- (c) Applied at only one level of the measurement process. 1

(36) Data validation criteria are documented and include:

- (a) Limits on: (1) operational parameters such as flow rates; (2) calibration data, (3) special checks unique to each measurement; e.g., successive values/averages; (4) statistical tests; e.g., outliers; (5) manual checks such as hand calculations. 5
- (b) Limits on the above type checks for most of the measurement systems. 3
- (c) Limits on some of the above type checks for only the high-priority measurements. 1

DATA VALIDATION PROCEDURES (continued)

SCORE

- (37) Acceptable limits as set are reasonable and adequate to insure the detection of invalid data with a high probability for:
- (a) All measurement systems. 5
 - (b) At least 3/4 of the measurement systems. 3
 - (c) No more than 1/2 of the measurement systems. 1
- (38) Data validation activities are:
- (a) Recorded on standard forms at all levels of the measurement process. 5
 - (b) Recorded in the operator's/analyst's log book. 3
 - (c) Not recorded in any prescribed manner. 1
- (39) Examination of data validation records indicates that:
- (a) Data validation activities have been carried out as specified and completely documented. 5
 - (b) Data validation activities appear to have been performed but not completely documented. 3
 - (c) Data validation activities, if performed, are not formally documented. 1
- (40) Data validation summaries are:
- (a) Prepared at each level or critical point in the measurement process and forwarded to the next level with the applicable block of data. 5
 - (b) Prepared by and retained at each level. 3
 - (c) Not prepared at each level nor communicated between levels. 1

DATA VALIDATION PROCEDURES (continued)

SCORE

(41) Procedures for deleting invalidated data are:

- | | |
|---|---|
| (a) Clearly defined in writing for all levels of the measurement process, and invalid data are automatically deleted when one of the computerized validation criteria are exceeded. | 5 |
| (b) Programmed for automatic deletion when computerized validation criteria are exceeded but procedures not defined when manual checks detect invalid data. | 3 |
| (c) Not defined for all levels of the measurement process. | 1 |

(42) Quality audits (i.e., both on-site system reviews and/or quantitative performance audits) independent of the normal operations are:

- | | |
|--|---|
| (a) Performed on a random but regular basis to ensure and quantify data quality. | 5 |
| (b) Performed whenever a suspicion arises that there are areas of ineffective performance. | 3 |
| (c) Never performed. | 1 |

PROCUREMENT AND INVENTORY PROCEDURES

SCORE

- (43) Purchasing guidelines are established and documented for:
- (a) All equipment and reagents having an effect on data quality. 5
 - (b) Major items of equipment and critical reagents. 3
 - (c) A very few items of equipment and reagents. 1
- (44) Performance specifications are:
- (a) Documented for all items of equipment which have an effect on data quality. 5
 - (b) Documented for the most critical items only. 3
 - (c) Taken from the presently used items of equipment. 1
- (45) Reagents and chemicals (critical items) are:
- (a) Procured from suppliers who must submit samples for test and approval prior to initial shipment. 5
 - (b) Procured from suppliers who certify they can meet all applicable specifications. 3
 - (c) Procured from suppliers on the basis of price and delivery only. 1
- (46) Acceptance testing for incoming equipment is:
- (a) An established and documented inspection procedure to determine if procurements meet the quality assurance and acceptance requirements. Results are documented. 5
 - (b) A series of undocumented performance tests performed by the operator before using the equipment. 3
 - (c) The receiving document is signed by the responsible individual indicating either acceptance or rejection. 1

PROCUREMENT AND INVENTORY PROCEDURES (continued)

SCORE

(47) Reagents and chemicals are:

- | | |
|---|---|
| (a) Checked 100% against specification, quantity, and for certification where required and accepted only if they conform to all specifications. | 5 |
| (b) Spot-checked for proper quantity and for shipping damage. | 3 |
| (c) Released to analyst by the receiving clerk without being checked as above. | 1 |

(48) Information on discrepant purchased materials is:

- | | |
|---|---|
| (a) Transmitted to the supplier with a request for corrective action. | 5 |
| (b) Filed for future use. | 3 |
| (c) Not maintained. | 1 |

(49) Discrepant purchased materials are:

- | | |
|---|---|
| (a) Submitted to a review by Quality Control and Chief Chemist for disposition. | 5 |
| (b) Submitted to Service Section for determination on acceptability. | 3 |
| (c) Used because of scheduling requirements. | 1 |

(50) Inventories are maintained on:

- | | |
|-------------------------------------|---|
| (a) First-in, first-out basis. | 5 |
| (b) Random selection in stock room. | 3 |
| (c) Last-in, first-out basis. | 1 |

PROCUREMENT AND INVENTORY PROCEDURES (continued)

SCORE

(51) Receiving of materials is

- | | |
|--|---|
| (a) Documented in a receiving record log giving a description of the material, the date of receipt, results of acceptance test, and the signature of the responsible individual. | 5 |
| (b) Documented in a receiving record log with material title, receipt date, and initials of the individual logging the material in. | 3 |
| (c) Documented by filing a signed copy of the requisition. | 1 |

(52) Inventories are:

- | | |
|--|---|
| (a) Identified as to type, age, and acceptance status. | 5 |
| (b) Identified as to material only. | 3 |
| (c) Not identified in writing. | 1 |

(53) Reagents and chemicals which have limited shelf life are:

- | | |
|---|---|
| (a) Identified as to shelf life expiration date and systematically issued from stock only if they are still within that date. | 5 |
| (b) Issued on a first-in, first-out basis, expecting that there is enough safety factor so that the expiration date is rarely exceeded. | 3 |
| (c) Issued at random from stock. | 1 |

PERSONNEL TRAINING PROCEDURES

SCORE

- (54) Training of new employees is accomplished by:
- (a) A programmed system of training where elements of training, including quality standards, are included in a training checklist. The employee's work is immediately rechecked by supervisors for errors or defects and the information is fed back instantaneously for corrective action. 5
 - (b) On-the-job training by the supervisor who gives an overview of quality standards. Details of quality standards are learned as normal results are fed back to the chemist. 3
 - (c) On-the-job learning with training on the rudiments of the job by senior coworkers. 1
- (55) When key personnel changes occur:
- (a) Specialized knowledge and skills are retained in the form of documented methods and descriptions. 5
 - (b) Replacement people can acquire the knowledge of their predecessors from coworkers, supervisors, and detailed study of the specifications and memoranda. 3
 - (c) Knowledge is lost and must be regained through long experience or trial-and-error. 1
- (56) The people who have an impact on quality; e.g., calibration personnel, maintenance personnel, bench chemists, supervisors, etc., are:
- (a) Trained in the reasons for and the benefits of standards of quality and the methods by which high quality can be achieved. 5
 - (b) Told about quality only when their work falls below acceptable levels. 3
 - (c) Are reprimanded when quality deficiencies are directly traceable to their work. 1

PERSONNEL TRAINING PROCEDURES (continued)

SCORE

(57) The employee's history of training accomplishments is maintained through:

- | | |
|--|---|
| (a) A written record maintained and periodically reviewed by the supervisor. | 5 |
| (b) A written record maintained by the employee. | 3 |
| (c) The memory of the supervisor/employee. | 1 |

(58) Employee proficiency is evaluated on a continuing basis by:

- | | |
|--|---|
| (a) Periodic testing in some planned manner with the results of such tests recorded. | 5 |
| (b) Testing when felt necessary by the supervisor. | 3 |
| (c) Observation of performance by the supervisor. | 1 |

(59) Results of employee proficiency tests are:

- | | |
|--|---|
| (a) Used by management to establish the need for and type of special training. | 5 |
| (b) Used by the employee for self-evaluation of needs. | 3 |
| (c) Used mostly during salary reviews. | 1 |

FEEDBACK AND CORRECTIVE ACTION

SCORE

- (60) A feedback and corrective action mechanism to assure that problems are reported to those who can correct them and that a closed loop mechanism is established to assure that appropriate corrective actions have been taken is:
- (a) Clearly defined in writing with individuals assigned specific areas of responsibility. 5
 - (b) Written in general terms with no assignment of responsibilities. 3
 - (c) Not formalized but left to the present supervisors/managers. 1
- (61) Feedback and corrective action activities are:
- (a) Documented on standard forms. 5
 - (b) Documented in the station log book. 3
 - (c) Documented in the operator's/analyst's notebook. 1
- (62) A review of corrective action records indicates that:
- (a) Corrective actions were systematic, timely, and fully documented. 5
 - (b) Corrective actions were not always systematic, timely, or fully documented. 3
 - (c) A closed loop mechanism did not exist. 1
- (63) Periodic summary reports on the status of corrective action are distributed by the responsible individual to:
- (a) All levels of management. 5
 - (b) One level of management only.
 - (c) The group generating the report only. 1

FEEDBACK AND CORRECTIVE ACTION (continued)

SCORE

(64) The reports include:

(a) A listing of major problems for the reporting period; names of persons responsible for corrective actions; criticality of problems; due dates; present status; trend of quality performance (i.e., response time, etc.); listing of items still open from previous reports.

5

(b) Most of the above items.

3

(c) Present status of problems and corrective actions.

1

CALIBRATION PROCEDURES

SCORE

- (65) Calibration procedures are:
- (a) Clearly defined and written out in step-by-step fashion for each measurement system and support device. 5
 - (b) Defined and summarized for each system and device. 3
 - (c) Defined but operational procedures developed by the individual. 1
- (66) Calibration procedures as written are:
- (a) Judged to be technically sound and consistent with data quality requirements. 5
 - (b) Technically sound but lacking in detail. 3
 - (c) Technically questionable and lacking in detail. 1
- (67) Calibration standards are:
- (a) Specified for all systems and measurement devices with written procedures for assuring, on a continuing basis, traceability to primary standards. 5
 - (b) Specified for all major systems with written procedures for assuring traceability to primary standards. 3
 - (c) Specified for all major systems but no procedures for assuring traceability to primary standards. 1
- (68) Calibration standards and traceability procedures as specified and written are:
- (a) Judged to be technically sound and consistent with data quality requirements. 5
 - (b) Standards are satisfactory but traceability is not verified frequently enough. 3
 - (c) Standards are questionable. 1

CALIBRATION PROCEDURES (continued)

SCORE

- (69) Frequency of calibration is:
- (a) Established and documented for each measurement system and support measurement device. 5
 - (b) Established and documented for each major measurement system. 3
 - (c) Established and documented for only certain measurement systems. 1
- (70) A review of calibration data indicates that the frequency of calibration as implemented:
- (a) Is adequate and consistent with data quality requirements. 5
 - (b) Results in limits being exceeded a small fraction of the time. 3
 - (c) Results in limits being exceeded frequently. 1
- (71) A review of calibration history indicates that:
- (a) Calibration schedules are adhered to and results fully documented. 5
 - (b) Schedules are adhered to most of the time. 3
 - (c) Schedules are frequently not adhered to. 1
- (72) A review of calibration history and data validation records indicates that:
- (a) Data are always invalidated and deleted when calibration criteria are exceeded. 5
 - (b) Data are not always invalidated and/or deleted when criteria are exceeded. 3
 - (c) Data are frequently not invalidated and/or deleted when criteria are exceeded. 1

CALIBRATION PROCEDURES (continued)

SCORE

(73) Acceptability requirements for calibration results are:

(a) Defined for each system and/or device requiring calibration including elapsed time since the last calibration as well as maximum allowable change from the previous calibration. 5

(b) Defined for all major measurement systems. 3

(c) Defined for some major measurements systems only. 1

(74) Acceptability requirements for calibration results as written are:

(a) Adequate and consistent with data quality requirements. 5

(b) Adequate but others should be added. 3

(c) Inadequate to ensure data of acceptable quality. 1

(75) Calibration records (histories) are:

(a) Utilized in revising calibration schedules (i.e., frequency). 5

(b) Utilized when specific questions arise and reviewed periodically for trends, completeness, etc. 3

(c) Utilized only when unusual problems occur. 1

FACILITIES/EQUIPMENT -

	SCORE
(76) Facilities/Equipment are:	
(a) Adequate to obtain acceptable results.	5
(b) Adequate to obtain acceptable results most of the time.	3
(c) Additional facilities and space are needed.	1
(77) Facilities, equipment, and materials are:	
(a) As specified in appropriate documentation and/or standards.	5
(b) Generally as specified in appropriate standards.	3
(c) Frequently different from specifications.	1
(78) Housekeeping reflects an orderly, neat, and effective attitude of attention to detail in:	
(a) All of the facilities.	5
(b) Most of the facilities.	3
(c) Some of the facilities.	1
(79) Maintenance Manuals are:	
(a) Complete and readily accessible to maintenance personnel for all systems, components, and devices.	5
(b) Complete and readily accessible to maintenance personnel for all major systems, components, and devices.	3
(c) Complete and accessible for only a few of the systems.	1

RELIABILITY

SCORE

- (80) Procedures for reliability data collection, processing, and reporting are:
- (a) Clearly defined and written for all system components. 5
 - (b) Clearly defined and written for major components of the system. 3
 - (c) Not defined. 1
- (81) Reliability data are:
- (a) Recorded on standard forms. 5
 - (b) Recorded as operator/analyst notes. 3
 - (c) Not recorded. 1
- (82) Reliability data are:
- (a) Utilized in revising maintenance and/or replacement schedules. 5
 - (b) Utilized to determine optimum parts inventory. 3
 - (c) Not utilized in any organized fashion. 1

APPENDIX B STANDARD TECHNIQUES USED IN
QUANTITATIVE PERFORMANCE AUDITS

Table 1. Physical measurements

Property	Measurement Methods	Calibration Methods	Audit Techniques
Density	a. Vibrating U-tube b. Mass/flow meter c. Bubble tube	Take sample, get weight and volume at process temperature and calculate density.	Frequency: Before start and at end of demonstration, monthly in between. Technique: Use of appropriate laboratory weight and volume measures.
Flow	a. Orifice meter i. manometer ii. differential pressure cell iii. mechanical gauges iv. electrical cells b. Pitot tube i. manometer ii. mechanical gauges iii. electrical cells iv. differential pressure cell c. Venturi meter d. Magnetic flow meter e. Ultrasonic flow meter	Primary method is to remove meter from process and calibrate on test stand. Secondary method is calibration of elements following sensor.	Frequency: Before start and at end of demonstration, monthly in between. Remove sensor element and inspect for corrosion or fouling. Carry out manufacturer recommended calibration procedure. For transducer and output, apply substitute signal and calibrate.
Humidity	a. Wet bulb/dry bulb thermometers b. Dewpoint meters c. Electronic humidity cells d. Fluidic	Calculation of humidity from wet and dry bulb measurements and psychrometric relations.	Frequency: Before start and at end of demonstration, weekly for wet/dry bulb, monthly for others. Technique: Remove sensor and subject to air stream having wet/dry apparatus for comparison.

Table 1. Physical measurements (con.)

Property	Measurement Methods	Calibration Methods	Audit Techniques
Level	a. Bubble tube b. Float c. Conductivity cell d. Capacitance cell e. Differential pressure cell f. Ultrasonic g. Sight glass	Measure level with sight glass or dip stick.	Frequency: Before start and at end of demonstration, monthly in between. Technique: Measure level at several points in range and compare to readout.
Pressure, differential pressure	a. Mechanical gauge b. Manometer c. Electrical pressure cell d. Differential pressure cell	Use of dead weight tester is primary standard. Secondary standards are a. Manometer with known fluid b. Precision mechanical gauges c. Standard electrical pressure cells	Frequency: Before start and at end of demonstration, monthly in between. Technique: Pressure sensors to be provided with test taps and valves, also tap for secondary source for d/p or electrical cells. Manometer is preferred for calibration in field where possible
Temperature	a. Thermocouple b. Resistance Temperature Detector c. Thermistor d. Filled bulb e. Mercury thermometer	Comparison to reference point a. Ice point H_2O b. Boiling point H_2O c. Standard thermometer d. Electronic standard	Frequency: Before start and at end of demonstration, monthly in between. Technique: Remove sensor, insert in reference temperature. For non-removable sensor, measure output of sensor, and insert substitute signal into instrument input and check calibration.

Table 2. Gas effluent streams

Material	Measurement Method	Calibration Method	Audit Techniques
Carbon Monoxide	Method 10 (Continuous)	Standard calibration gas.	Provide SRM* for measurement.
Nitrogen Oxide	Method 7 (Grab)	Calibrate Sampling Train components and use control samples for analysis phase.	1. Independent duplicate sampling and analysis. 2. Review and observe operating procedures, check calibration of train components, and prepare blind samples for field team to measure.
Particulates	Continuous	1. Use standard calibration gases plus 2. Compare results to Method 7.	1. Provide NO/NO ₂ calibration gas: NBS-SRM (Analysis phase). 2. Compare to Method 7 (total measurement method).
	Method 5 (Sampling Train)	Calibrate components of sampling train: pitot tube, dry gas meter, orifice meter, temperature measurement devices, probe heater, filter holder, temperature system	1. Audit of total method by independent, simultaneous measurement from sampling through analysis. 2. Calibration check on sample train components per cent isokinetic rate, and visual observation of operating procedures.
	Optical (transmissometer)	Filters	Calibration check with independent set of NBS filters.

* Standard Reference Material, from the National Bureau of Standards.

Table 2. Gas effluent streams (con.)

Material	Measurement Method	Calibration Method	Audit Techniques
Sulfur Dioxide	Method 6 (Batch)	Calibrate sampling train components and use standards samples for analysis phase.	1. Independent duplicate sampling and analysis. 2. Review/observe operating procedures, check calibration of train components, and analyze split samples and/or prepare blind samples for field team to measure.
	Method 12 (Continuous)	1. Use standard calibration gases plus 2. Use calibrated absorbance filter furnished by instrument manufacturer.	1. Compare to Method 6. 2. Provide SRS for measurements.

Table 3. Liquid streams, suspended solids

Material	Measurement Method	Calibration Method	Audit Techniques
Liquid Stream Samples— per cent solids, ionic species	Standard chemical and in- strumental techniques (atomic absorption spec- trometry, potentiometry, amperometry, etc.)	Calibrate glassware, balances, instruments.	Control samples, split sam- ples.
Effluent solids; e.g., per cent water, CaO, SO ₃ , SO ₄ ⁻² , CO ₂ , inerts, etc.*	Standard gravimetric, vol- umetric, instrumental techniques (such as x-ray fluorescence).	Calibrate volumetric, gravi- metric, instrumental measure- ment devices (glassware, balances, meters, etc.)	Control samples, split sam- ples.
pH	a. pH cell b. Indicators (test papers) c. Wet chemical	a. Subject to known pH buffer solution b. Sample stream and measure pH with independent method/instrument.	Frequency: Daily to weekly Technique: Remove pH cell from process and insert in buffered solutions in range of process pH.

* typical of solids composition in the effluent of a wet limestone SO₂ scrubber.